

REMARKS**Claim amendments**

Claim 98 is canceled solely to expedite prosecution in this application, without disclaimer or prejudice to its presentation in a continuing or other related application.

Status of outstanding Office action

Because the Office letter mailed on 17 July is docketed as a final action in PAIR/PALM, applicant is filing this response with the Office's electronic filing facility as an after-final submission. The form PTOL-326 also indicates that the action is final. However, the body of the Office action does not include any indication that the action is in fact final. *See, e.g.*, MPEP § 706.07 (final rejection should conclude with Form Paragraph 7.39, per the Office's consistent practice).

The 17 July Office action contains new grounds of rejection based on a published application cited by applicant prior to the preceding Office action. *See* IDS filed 20 October 2006. Also, the reference publication is based on a continuation of a U.S. patent previously made of record, U.S. Patent No. 6,455,043 B1. *See* references cited with Office action mailed 19 April 2004. The new grounds of rejection were not necessitated by amendment or other action by the applicant.

For these reasons, applicant believes that the action should not be final and requests that the examiner clarify the status of the application.

Information Disclosure Statements

The Office has not yet indicated consideration of the disclosure statements filed on 1 May 2003 (resubmitted on 11 October 2006), 26 September 2003, 19 May 2004, and 20 October 2006. Applicant requests that the Office return the corresponding initialed form PTO-1449s with the next Office communication.

Rejection under 35 U.S.C. § 112, first paragraph

Claim 98 was rejected under § 112, first paragraph, as allegedly containing new matter. By the amendment above, applicant has canceled claim 98. Accordingly, the rejection under § 112, first paragraph, is moot. However, for the reasons below, applicant does not agree that the claim did not comply with the description requirement.

The Office questions support for the particular combination of limitations in claim 98. In particular, the Office action states that the passages cited by applicant as providing support for the claim “are not sufficient to provide support to … treating CLL with an anti-CD20 antibody combined with one additional therapy devoid of another therapy.”

Original claim 8 forms a part of the disclosure as filed. Rewritten in the form of an independent claim, claim 8 is directed to:

[Claim 1] A method of treating a hematologic malignancy associated with high numbers of circulating tumor cells by administering a therapeutically effective amount of an anti-CD20 antibody or fragment thereof,

[Claim 3] wherein said malignancy is B-prolymphocytic leukemia (B-PLL) or chronic lymphocytic leukemia (CLL),

[Claim 8] and wherein said antibody is administered in combination with radiation, chemotherapy, and/or lymphokine administration.

The limitation of claim 8 conveys that the treatment may include *or exclude* any of the recited alternatives, provided that at least one of the alternatives is chosen. Thus, the claim defines a small genus of combinations, namely –

Treatment of B-PLL or CLL using anti-CD20 antibodies,
 ± radiation
 ± chemotherapy
 ± lymphokine administration.

The specific combination of (CLL, + chemotherapy, - radiation, ± lymphokine administration) corresponds to a composite of two out of 14 possible combinations covered by this claim. The law of anticipation establishes that the description of a genus comprising a small number of discrete alternatives may suffice to describe every member of that genus individually for a person skilled in the art. *See, e.g., In re Petering*, 301 F.2d 676, 681, 133 USPQ 275, 279-80

(C.C.P.A. 1962); MPEP § 2131.02. In this case, the genus of combinations is sufficiently limited that one of skill would “immediately envisage” each combination of the inclusions and exclusions specified in claim 8. Thus, the application as filed describes the subject matter of claim 98.

Applicant notes that the subject matter of claim 98 is fully covered by remaining generic claims, e.g., claims 55 and 97.

Rejection under 35 U.S.C. § 102(e)

The Office has rejected claims 29, 39-44, 46-50, 55, 65-70, 72-76, 81-89, and 94-98 under § 102(e) as anticipated by U.S. Patent Application Publication No. 2003/ 0026804. Applicant respectfully traverses this ground of rejection.

The allegedly anticipatory disclosure cited as the basis for the rejection does not appear in the priority document for the cited reference. Accordingly, that disclosure is not entitled to an effective filing date of 11 August 1998.

Specifically, U.S. Patent Application Publication No. 2003/ 0026804 is based on serial no. 10/196,732, filed 17 July 2002, which claims priority to nonprovisional application no. 09/372,202, filed 11 August 1999, and to provisional application no. 60/096,180, filed 11 August 1998. The disclosure of the provisional application is not the same as the disclosure of the later nonprovisional applications. In particular, the teachings identified in the final Office action at page 6, in the paragraph bridging from page 5, do not appear in the 11 August 1998 provisional application. Accordingly, the disclosure cited in the present rejection under § 102(e) is not entitled to an effective filing date that precedes 9 November 1998, the filing date of provisional application no. 60/107,658 to which this application claims priority.

Applicant requests that the Office reconsider and withdraw the rejection under § 102(e).

Rejection under 35 U.S.C. § 103(a)

Claims 29-98 have been rejected under § 103(a) over the combination of U.S. Application Publication No. 2003/ 0026804; Kaminski '365; McLaughlin (*J. Clin. Oncol.*, 1998); Stenbygaard (*Br. Cancer Res. Treatment*, 1993); and Lerner (US 6,399,649). Applicant traverses this ground of rejection.

For the reasons discussed immediately above with respect to the rejection under § 102, the cited disclosure of published application no. 2003/ 0026804 is not prior art to this application under § 102(e).

Applicant also states that at the date that the invention claimed in this application was made, the invention described and claimed in this application and the priority applications for the reference published patent application, patent application publication no. 2003/ 0026804, were owned by and/or subject to an obligation of assignment to IDEC Pharmaceuticals Corp., which now conducts business as Biogen Idec Inc. Accordingly, the '804 application is not prior art to the claims of this application under §§ 102(e)/103. *See* 35 U.S.C. § 103(c); MPEP §§ 706.02(l)(2), (3).

Furthermore, for the reasons discussed at pages 14-16 of the reply filed 27 April 2007, the secondary references (which were all the references cited in a previous, now-withdrawn rejection under § 103(a)) do not provide the teachings necessary to establish a *prima facie* case of obviousness with respect to any pending claim.

Applicant requests that the Office withdraw the rejection under § 103(a).

Conclusion

Applicant believes that this reply fully responds to all of the rejections stated in the last Office action and respectfully requests that they be withdrawn.

The examiner is invited to contact the undersigned attorney should she have any questions concerning the application.

Respectfully submitted,

/David L. Fitzgerald/

David L. Fitzgerald, Reg. No. 47,347
Attorney for Biogen Idec Inc.

SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005
tel. (202) 736-8818
fax (202) 736-8711